

INFORMATION FOR PATIENTS

Coaptite®

For the Treatment of Stress Urinary Incontinence in Women

This brochure is to help you decide if you should have a Urethral Bulking Procedure with Coaptite® for the treatment of stress urinary incontinence. Please read this entire brochure and talk about it with your doctor. Your doctor will answer all of your questions before you decide what to do.

BioForm Medical, Inc.
4133 Courtney Road
Suite 10
Franksville, WI 53126

Toll Free: (866) 862-1211

Date Printed:
November 2005

Table of Contents

	Page No.
Glossary of Terms	3
Introduction	5
Contraindication	5
Warnings	5
What are the risks of Coaptite[®] injections?	6
Are there other options?	6
What are the benefits of Coaptite[®] injections?	6
What can I expect during my procedure with Coaptite[®]?	7
Can I go back to normal activity?	8

Glossary of Terms

Bladder:	Sack-like organ in the lower abdomen where urine is stored for elimination from the body.
Calcium Hydroxylapatite:	A natural occurring material that is found in bones and teeth.
Coaptite®:	A material used to bulk or fill out the tissues surrounding the urethra to provide additional support during physical activity. Coaptite® is made of round particles made of calcium hydroxylapatite.
Contraindications:	A statement in the product information that, if the product is used for a certain condition, you may be harmed. For example, Coaptite® is contraindicated for patients who have urinary tract infection at the time of treatment.
Cystoscope:	An optical instrument placed in the urethra to enable the physician to examine directly inside the urethra and bladder.
Erode/Erosion:	The breakdown of the tissue that covers the Coaptite® material.
Exposed bulking material	When the Coaptite® leaks out of your tissue.
Frequent urination:	Condition where you need to go to the bathroom to urinate many times during the day and night, more than 8-12 times a day.
Hysterectomy:	Removal of your uterus.
Urinary Retention:	Condition where you are unable to urinate because your urethra is blocked.
Risk:	Complication that may result from the procedure.
Stress Urinary Incontinence (SUI):	The accidental leakage of urine during exercise or physical activities such as coughing, sneezing, laughing, or other body movements that put pressure on the bladder. SUI is the most common type of urinary problem in younger and middle age women. In some cases, it is related to childbirth. It may also begin around the time of menopause.
Urethra:	The tube that carries urine from the bladder to outside the body for elimination.
Urethral Bulking:	The injection of material (bulking agent) into the tissues surrounding the urethra to help the urethra close to avoid

accidental leakage. Urethral bulking does not close the urethra totally; the urethra can still open normally to allow for urination.

Urethral Sphincter: A circular muscle around the urethra that opens it when you want to urinate but keeps it closed at other times.

Urethral Stricture: An abnormal narrowing or "kink" in the urethra that may prevent normal urination. Coaptite® should not be used if a urethral stricture is not corrected.

Urgency: A strong desire to urinate but does not result in accidental leakage or an episode of incontinence.

Urinary Tract Infection: Condition where the presence of bacteria in urine cause frequent urination and pain during urination.

Vascular Disease: Damage to your arteries from diabetes, high blood pressure, high cholesterol, and smoking.

Warnings: A statement in the product information that alerts you to a potentially harmful condition in which you should contact your physician.

Coaptite® Patient Brochure

Introduction

Coaptite® is a material used to bulk or fill out the tissues surrounding the urethra to provide additional support during physical activity. Coaptite® is made of round particles made of calcium hydroxylapatite, which is a natural component of your teeth and bones, in a water-based gel.

Stress Urinary Incontinence is the involuntary loss of urine during physical activity such as coughing, laughing or sneezing. The round muscle (sphincter) used to keep urine in the bladder can become weak and urine leaks out during these activities. This type of incontinence is treated both surgically and non-surgically. Bulking with Coaptite® increases the resistance of the urethra to urine leakage.

This brochure is to help you make a decision as to whether or not to have a urethral bulking procedure with Coaptite®. Over 13 million adults have Stress Urinary Incontinence in the United States, 85% of these adults being women. Coaptite® treatment is only one way to treat Stress Urinary Incontinence. Your physician will provide you with recommended options for treating your incontinence and help you make the right treatment decision.

Contraindication

- You should not have the procedure at this time if you have inflammation of the bladder (cystitis) or the urethra (urethritis) or other infections. Tell your doctor if you have pain when you urinate or if you urinate often because these may be signs of an urinary tract infection. After your infection is treated, using Coaptite® treatment can be considered.

Warnings

- Narrowing of the bladder neck or urethra is called a urethral stricture. Your urethra could be blocked and you may not be able to pass urine if you are treated when you have these strictures. Tell your doctor if you have to strain in order to start urinating. This may be a symptom of a stricture. Your doctor will be able to discuss the treatment options for urethral strictures.
- Safety and effectiveness of Coaptite® in pregnant women is unknown. It is unknown whether Coaptite® treatment will harm you or your baby if you are pregnant. It is unknown whether Coaptite® treatment will relieve your stress urinary incontinence if you are pregnant.
- If your doctor injects too much Coaptite®, you may not be able to urinate. If this happens, the doctor may have to put a catheter in you until you can urinate normally.
- Coaptite® may not stay in place where it is injected and this can lead to complications.

- Coaptite® may erode through your tissue. If that happens, further care including major surgery may be needed to correct the problem. In the study, 2 out of 158 patients developed this problem and one of these patients had to have surgery to correct the problem.
- Women with vascular disease and prior pelvic surgery, e.g., hysterectomy or surgery for urinary incontinence, may be at increased risk for tissue erosion.
- Contact your doctor if you have any problem that bothers you or lasts longer than 24 hours after your Coaptite® bulking procedure. If you do not contact your doctor, your problem may get worse and harm you.

What are the risks of Coaptite® injections?

In the clinical study, 158 patients were treated with Coaptite® and followed for 12 months after the initial treatment. The adverse events reported included:

- ♦ Retention (41%)
- ♦ Blood in the urine (20%)
- ♦ Painful urination (15%)
- ♦ Urinary tract infection (8%)
- ♦ Urgency (8%)
- ♦ Frequent urination (7%)
- ♦ Exposed bulking material (1%)

Most of these adverse events listed above happened within 24 hours and went away within 30 days.

Coaptite® did not stay in place where it was injected. As a result, two patients experienced a serious adverse event. One required corrective surgery and the other did not. See the Warning Section above for more information.

You may require more than one treatment to achieve dryness or satisfactory improvement, or Coaptite® may not help at all.

It is unknown how long Coaptite® treatment will last. So far it has been shown to last at least one year. Over time, the calcium hydroxyapatite (CaHA) particles should break down and be taken up by the body. Some data shows that the CaHA particles can still be there after 3 years, but everyone is different and they may not be there as long for you.

Are there other options?

There are also other ways to treat your problem. They can be non-surgical, including strengthening exercises for the pelvic muscles to improve support of the bladder and urethra, and biofeedback to assist in retraining the pelvic muscles. Drugs, as well as treatment with other bulking agents can help. Surgical procedures can repair and reposition organs, restore support to weakened pelvic muscles, or implant an artificial urinary sphincter. You should discuss these treatment options with your doctor.

What are the benefits of Coaptite® injections?

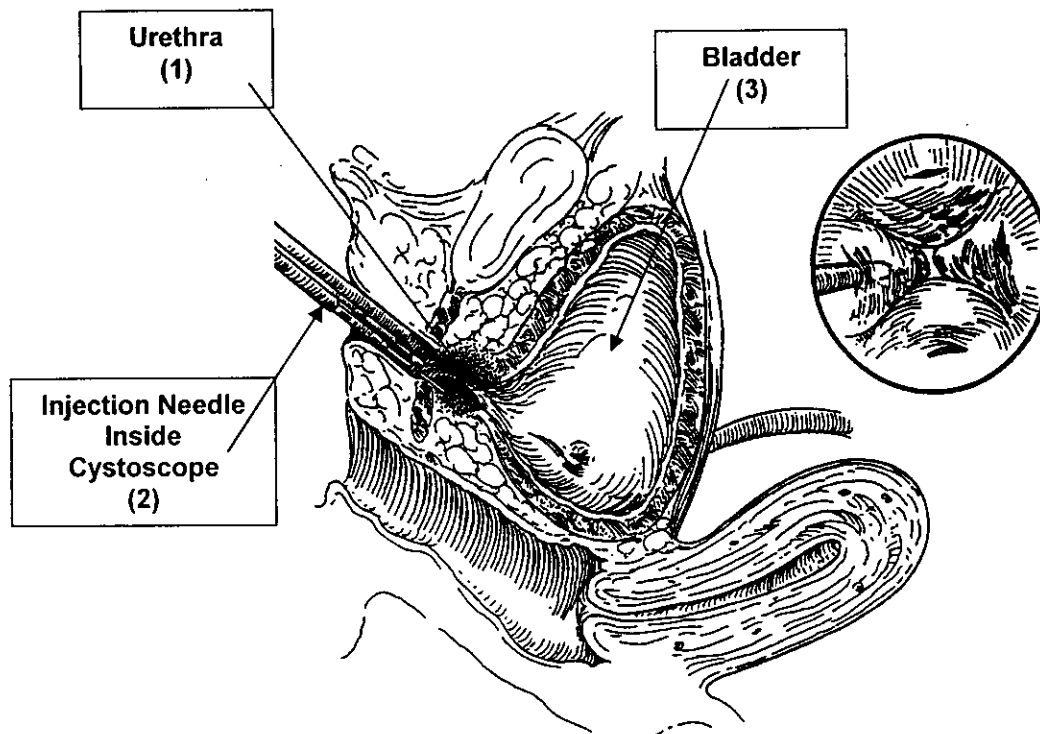
Coaptite® may benefit you because it may help you become dry or lessen the amount of urinary leakage. Coaptite® is made of round particles of CaHA in a water-based gel. The body takes up the gel. The particles remain to act as a space filling bulk, causing the closing of the urethra.

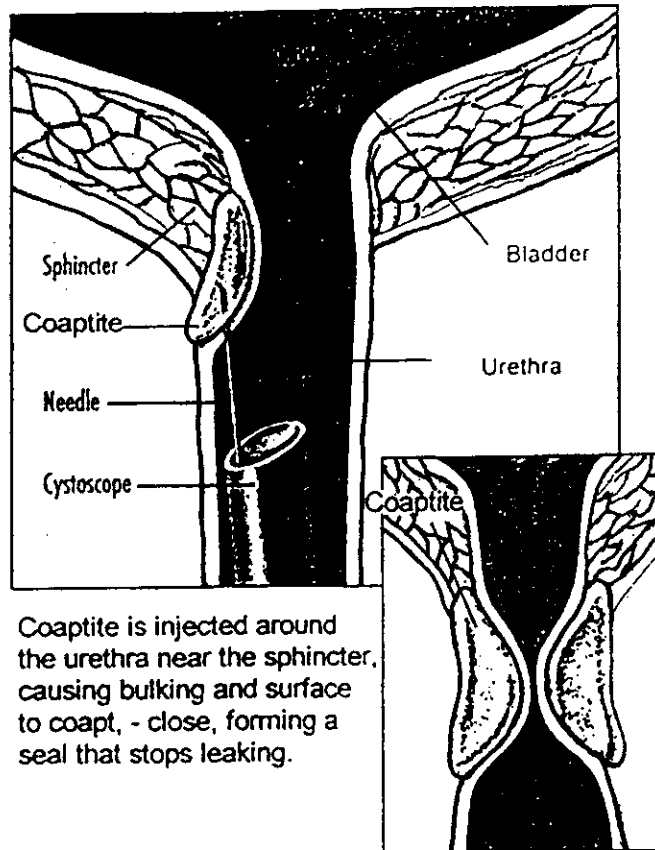
In the study, 83 out of 131 (63%) of patients were improved at 12 months following treatment with Coaptite®. Fifty-one out of 131 (34%) of the patients were dry. A majority of the patients (82 out of 131) (62%) had more than one injection of Coaptite®. Thirteen of 131(10%) patients got worse after one year. For 35 patients (27%), we do not know if they improved remained the same or got worse.

What can I expect during my procedure with Coaptite®?

The procedure will take place in doctor's office, an outpatient surgery center or in an operating room. The procedure takes approximately 15-20 minutes. Your doctor will determine what type of anesthesia is best for you. During the procedure, a needle is placed into the urethra (See note 1 in the picture below) using a cystoscope (see note 2 in the picture below) and Coaptite® is injected into the tissues surrounding your urethra providing a bulking effect. The doctor removes the needle and the procedure is completed. After the procedure, you will stay in the office or recovery room until you are able to pass urine on your own, usually within a few hours.

Your doctor will talk to you so you know what to expect from your treatment.





Can I go back to my normal activity after I go home?

Your physician will give you specific instructions regarding your activity level after your procedure. Most people return to normal activity within one to two days.